ximedica®

# You and the FDA
## Medical Device Applications for Pre-Submission Review


Written by
**Kimberly Waller, Ph.D.**
Regulatory and Human Research Affairs Lead at Ximedica

*Prior to coming to Ximedica, Kimberly spent several years doing research in the Center for Biomedical Engineering at Brown University, Warren-Alpert Medical School of Brown University and Rhode Island Hospital. She obtained her Ph.D. in Biomedical Engineering from Brown University and her B.S. in Biomedical Engineering from Boston University.*


### Pre-submissions: Who, When, Why?

As with any relationship, communication is key, and the company-FDA relationship is no different. Effective communication with the FDA will allow your company to form a solid regulatory plan, reduce burden on your reviewer, and eliminate the need for lengthy re-writes. Remember that you are expert on your specific product and FDA is not. It is in your interest to share key information with the FDA staff who will be reviewing your marketing application. Consider them to be your partner on the road to market; working together benefits both parties.

### Why?

Pre-submissions (Pre-Subs) allow a manufacturer to have key questions about regulatory requirements and performance data expectations addressed prior to submission. Pre-Subs minimize difficult, time-consuming questions from the FDA after submitting your marketing application.

Pre-Subs are a gateway to communication with the FDA that provide clear, functional forums for companies to receive a "check" on their activities to date and a confirmation on activities that are in the works. Think of pre-subs as opportunities to explore FDA's reaction to your product development strategies and tactics, particularly if you are proposing something new or unfamiliar.

### When?

Scheduling a pre-sub is very helpful for gaining early feedback from the FDA. While you need to have a solid list of your product's features and functions, don't wait until you have a final design. Be prepared to discuss the risks and benefits of your product and how your design will ultimately reduce risks. If you think your product will compare favorably with what is already available, show the Agency why you believe that is true. When you are planning the timing of your Pre-Sub submission, remember that FDA feedback times in the form of a written response will arrive in 75-90 days, with additional time needed to coordinate a teleconference or face-to-face meeting.

### How?

The questions posed to FDA are the most important portion of the pre-submission meeting or document; however, the phrasing of the questions is vital to the success of the manufacturer's bid.

Present the FDA with the work that has been completed, present possible options moving forward, including pros and cons of each, and conclude with the best course of action, in your opinion, with justification. Presenting your argument in a balanced, unbiased manner allows the reviewer to make an informed decision with minimal burden.

Remember the needs of your audience! FDA reviewers are often working on multiple documents across various therapeutic areas, simultaneously. Do not burden your reviewer with unfamiliar jargon or inconsistent terms; instead, respect your reviewer's time and effort by delivering documents and presentations that are clear, concise and compelling. Remember, you and your reviewer are on the same side! Work with them towards the common goal of bringing your product to market.

### How often?

Before you contact the FDA with questions, make sure you have done your homework. Contact outside regulatory consultants, attend FDA-sponsored events and meetings, and read FDA guidance.

According to FDA guidance, the Pre-Sub program is not meant to be an iterative process, (i.e., one in which FDA considers the same or similar information more than once); however, in the case of new technologies, numerous pre-submissions may be appropriate for determining the proper regulatory plan for a product.

If your company plans to have numerous pre-submissions, outline your plan in the initial meeting. This approach allows the FDA to plan for upcoming meetings and benefits. If your product does not incorporate new technologies or propose a new indication for use and you still want a Pre-Sub response, consider asking for a written response rather than a meeting.

Remember, the pre-sub process is not meant to "guide" a manufacturer to market or write their regulatory plan; it is designed to answer specific questions that are not outlined in guidances. Demonstrate that you have done your due diligence by knowing the regulatory review pathways available and the expectations detailed in relevant guidance documents. If you are proposing a process or information different than what is described in FDA guidance, be prepared to justify your approach.

> **"BEFORE YOU CONTACT THE FDA WITH QUESTIONS MAKE SURE YOU HAVE DONE YOUR HOMEWORK"**

### Adjust your expectations

Applicants should recognize that even though the Agency may have already reviewed the study protocols/plans in a Pre-Sub, this does not guarantee approval or clearance of future submissions. New information may arise between the Pre-Sub and the submission, including changes in standard of care or scientific advances.

Pick your battles wisely! FDA guidance, while not binding, is published to help manufacturers get to market. If you do not follow FDA guidance, be ready to provide compelling justification and convince your reviewer, in a respectful way. If guidance includes a requirement that you deem unnecessary, but would satisfy the expectations of the FDA, it may be best to comply.

### Do your homework

- Did you follow FDA guidance and draft guidance documents?
- Are you familiar with FDA processes such as selecting the appropriate PMOA for combination products or specific regulations for the device you are making?
- If submitting a 510(k), have you chosen a predicate?
- Outline all non-clinical and clinical studies in detail – the FDA will not be writing these for you!

### Conclusion

Pre-subs are a great way to introduce your product to the FDA, to learn what concerns and expectations they have about your product type, and to smooth out the path to getting your product to market. Engaging the FDA early in the design of your product development and regulatory plan will increase communication between your company and FDA and help avoid pitfalls in the submission process.

FDA REGISTERED ISO CERTIFIED NSAI CERTIFIED

Ximedica is a full-service ISO 13485-certified and FDA-registered product development firm. For 30 years Ximedica has provided a unique growth platform enabling organizations to successfully deploy medical technology products into the market.

ximedica®

55 Dupont Drive, Providence, RI 02907, USA | T: +1 401 330 3163

Providence | Minneapolis | San Francisco | Silicon Valley | Hong Kong